

# Notice of Allowability

## Application No.

10/540,848

## Examiner

Bao-Thuy L. Nguyen

## Applicant(s)

CHUNG ET AL.

## Art Unit

1641

### - The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to RCE filed 12/08/08.
2. ☒ The allowed claim(s) is/are 6 and 8 which have been renumbered from 1-2 respectively.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of the:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.  
(a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached  
1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.  
(b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.  
**Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

## Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08),  
Paper No./Mail Date 9/11/08
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_.  
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_.

### EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.
2. Authorization for this examiner's amendment was given in a telephone interview with D.J. Stockley on February 23, 2009.

The application has been amended as follows:

In the claims:

Claim 6 (currently amended) A method for diagnosing liver disease ~~[in]~~ selected from a group consisting of chronic hepatitis, liver cirrhosis and ~~[hepatocarcinoma]~~ hepatocarcinoma with liver cirrhosis, comprising:

contacting a monoclonal antibody which reacts only with asialo  $\alpha$ 1-acid glycoprotein and ~~[excludes]~~ does not react with heptoglobin and  $\alpha$ 2-macroglobulin and lectin RCA (Ricinus communis agglutinin) recognizing asialo glycoprotein with a test sample to measure an amount of asialo  $\alpha$ 1-acid glycoprotein (AsAGP), in which the monoclonal antibody is the subclass IgG<sub>1</sub> produced from the mouse cell line deposited with the Korea Research Institute of Bioscience and Biotechnology having accession number KCTC 10261 BP;

measuring an amount of complexes formed between the antibody and AsAGP in the test sample; and

relating a measured amount of AsAGP in the test sample to a diagnosis of whether the test sample is from a person having the liver disease, wherein the liver disease is ~~[in a]~~ selected

from the group consisting of chronic hepatitis, liver cirrhosis and [heptacarcinoma]  
hepatocarcinoma with liver cirrhosis, and

wherein a cutoff value for diagnosing that the test sample is from the person having [the]  
said liver disease [in the group consisting of chronic hepatitis, liver cirrhosis and  
heptacarcinoma with liver cirrhosis] is above 1.50 µg/ml.

***Reason for Allowance***

3. The following is an examiner's statement of reasons for allowance: the claims define over the prior art of record because the prior art of record, WO 01/35105 for example, fails to teach or make obvious a method using a monoclonal antibody, produced by the mouse cell line having accession number KCTC 10261 BP, for detecting asialo  $\alpha$ 1-acid glycoprotein in a test sample and relating the amount detected to a diagnosis of chronic hepatitis, liver cirrhosis and hepatocarcinoma with liver cirrhosis if the amount detected is above 1.50 µg/ml.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Monday – Thursday from 9:00 a.m. - 3:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bao-Thuy L. Nguyen/  
Primary Examiner, Art Unit 1641  
February 14, 2009